

REMARKS

Claims 48, 50, 53-55 and 74-94 are pending, with claims 74, 82, and 89 being independent. Applicants have amended claims 74, 82, and 89.

The Examiner has rejected independent apparatus claims 74 and 82 as anticipated by Cosman et al. (1984), obvious over Cosman et al. (1984) in view of Cosman '597, and anticipated by Makower et al. The Examiner has further rejected claim 74 as obvious over Cosman et al. (1984) in view of Makower et al. The Examiner has rejected independent method claim 89 as anticipated by or obvious over Makower et al.

The Examiner's action states:

Applicant appears to be arguing the claims as though they recite the thermal sensor as being enclosed, rather than embedded within the conductive material. To the extent that applicants are arguing that the sensor is merely embedded, the rejections of the apparatus claims set forth in the previous office action still apply (see e.g. temperature sensors 46 in figures 17 and 18 of Makower et al which having a surface flush with the surface of sheath 98 are embedded in the material therein, with the surfaces of elements 46 perpendicular to and opposite of the exposed surface being surrounded by conductive material). To the extent that applicants are arguing that the sensor is completely enclosed by the conductive material, these arguments are narrower than the claim language and are not convincing for this reason alone. However, such claims would also be anticipated/obvious in view of the rejections based on Cosman et al (1984).

In either case, the particular physical configuration does not manipulatively affect the claimed methods, thus the rejections based on Makower et al still apply.

Applicants have amended apparatus claims 74 and 82 to recite "a sensor completely enclosed by the thermally conductive material." As conceded by the Examiner, neither Makower et al. nor Cosman '597 describe or suggest a sensor completely enclosed by the thermally conductive material. Therefore, we address the Examiner's assertion that such claims would be anticipated/obvious in view of Cosman et al. (1984).

Claim 74 relates to an apparatus including an energy delivery device having a proximal portion and a distal portion, and configured to deliver sufficient energy to a selected site to effect a contraction in at least a portion of collagen containing tissue at the selected site. The distal

portion includes. The apparatus includes a sensor completely enclosed by the thermally conductive material and positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium. The sensor produces a thermal feedback signal which represents a composite of the thermal energy detected from the selected site of the collagen containing tissue and from the fluid medium. The energy delivery device includes circuitry for supplying the thermal feedback signal to a feedback control system for adjusting a level of energy delivered by the energy delivery device to at least the portion of the selected site of the collagen containing tissue.

Claim 74 is patentable over Cosman et al. (1984).

Cosman et al. (1984) describes a DREZ electrode having a small "sharpened tip with a built-in thermocouple sensor [that] can easily penetrate the spinal cord with minimal mechanical disturbance to the tissue and specific target positioning" (page 948, col. 1). Proximal of the tip is an insulated portion of the shaft of the instrument. The tip is 2 mm long, and "[v]ery importantly, the insulation has a stepped shoulder at its margin with the exposed lesion tip. This prevents the tip from penetrating the cord more than 2 mm, which is essential to controlling the longitudinal size of the lesion, by stabilizing the electrode's position against the pia even when it is hand-held" (page 948, col. 1).

There is no description or suggestion in Cosman et al. (1984) that the built-in thermocouple sensor is completely enclosed by thermally conductive material. However, to expedite prosecution, applicants have amended claim 74 to recite that the sensor is "positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium." As described in applicants' specification at, e.g., page 17, line 19 to page 18, line 13, the position of the sensor within the thermally conductive material is a determining factor of whether thermal energy is detected from the selected site and from an adjacent fluid medium. In Cosman et al (1984), the thermocouple is built-in to the tip of the device and the entire 2 mm tip is designed to penetrate the cord. Therefore the thermocouple is positioned to detect thermal energy from only the selected site, i.e., the cord.

Therefore, applicants submit that claim 74 and its dependent claims are patentable over Cosman et al. (1984). Furthermore, neither Makower et al. nor Cosman ('597) overcome the deficiencies in Cosman et al. (1984).

Therefore, applicants submit that claim 74 and its dependent claims are patentable over Cosman et al. (1984). Furthermore, neither Makower et al. nor Cosman ('597) overcome the deficiencies in Cosman et al. (1984).

Claim 82 likewise recites "a sensor completely enclosed by the thermally conductive material, the sensor being positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium." Therefore, applicants submit that claim 82 and its dependent claims are patentable over Cosman et al. (1984), Makower et al. and Cosman ('597) for at least the reasons discussed above.

Claim 89 relates to a method of delivering energy. As quoted above, the Examiner's action states: "In either case, the particular physical configuration does not manipulatively affect the claimed methods, thus the rejections based on Makower et al still apply." Applicants have amended claim 89 to recite "providing...a sensor completely enclosed by the thermally conductive material, the sensor being positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium." Therefore, applicants submit that the claimed methods include providing the particular physical configuration and thus claim 89 and its dependent claims are patentable over Makower et al. Furthermore, applicants submit that claim 89 and its dependent claims are patentable over Cosman et al. (1984), Makower et al., and Cosman ('597) for at least the reasons discussed above with respect to claim 74.

An Information Disclosure Statement was filed in the above-identified patent application on March 23, 1999. Two references submitted in that IDS was neither crossed-out nor initialled when the Examiner returned the Form PTO-1449 which was attached to the Office Action mailed January 31, 2000. Specifically, the Examiner did not indicate that the references of Wilkins et al., "Neurosurgery: Method of Making Nervous System Lesions," ch. 337, pp.2490-2499 and Sluyter, "Radiofrequency Lesions in the Treatment of Cervical Pain Syndromes," Radionics, Inc., 1989, have been considered.

It is therefore requested that the Examiner consider the references and indicate his consideration on the attached copy of the initialled Form PTO-1449.